UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Devices Products Liability Litigation	MDL No. 15-2666 (JNE/DTS)
This Document Relates To: ALL ACTIONS	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO 3M'S MOTION FOR RECONSIDERATION OF THE DECEMBER 13, 2017 *DAUBERT* ORDER

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INTRODUCTION

The Court's initial *Daubert* order considered hundreds if not thousands of pages of legal argument, literature, reports, internal documents, and deposition testimony of experts and study authors. 3M now proclaims that "compelling circumstances" emerged in the *Gareis* trial and afterwards that undermine both of Plaintiffs' theories of causation. This is pure subterfuge. There are no new revelations from the *Gareis* trial that the Court did not already consider. Nor is there any new groundbreaking evidence that calls into question the foundation for Plaintiffs' experts' opinions. Instead, 3M has thrown up yet another smokescreen of mischaracterizations and faux science in a blatant attempt to re-litigate settled issues of general causation. When the smoke clears based on the law and science presented herein, this Court will see that none of 3M's arguments justify reconsideration.

The Gareis Ruling on Internal Contamination Does Not Apply to Other Cases.

3M asserts that the Court's evidentiary ruling in *Gareis* on Plaintiffs' contamination theory broadly applies to *all* cases. To the contrary, the Court has expressly refused to apply case-specific rulings in *Gareis* to other bellwether cases. The Court's exclusion of this evidence in *Gareis* was based not on general causation opinions, but on the lack of evidence to support Dr. Jarvis's specific causation opinion. Because 3M hinged its motion for reconsideration on this red herring, it unravels altogether with the pull of a single string.

Dr. Elghobashi's Testimony and CFD Supports the Airflow Disruption Theory.

Elevating form over substance, 3M also argues that Elghobashi's objection to the terms "laminar" and "force field" disproves Plaintiffs' airflow disruption theory. *Au contraire*, Elghobashi's CFD showed that heat plumes from Bair Hugger collided with

turbulent overhead airflow and dispersed squames over the operating table. While Elghobashi's model and other studies did not measure every other source of heat and turbulence, those uncontrolled variables would have exacerbated—not ameliorated—Bair Hugger's spread of squames over the sterile field. Indeed, in just 45 seconds, Elghobashi's CFD showed a statistically significant number of squames in the sterile field near the wound. This effect would only be compounded by additional particles landing on the joint over the course of surgery—a fact confirmed by Darouiche et al. All told, Elghobashi's seminal work together with other published research provides a consistent reliable basis for the conclusion that Bair Hugger causes airborne contamination during joint surgery.

The Jeans Study Neither Disproves Nor Detracts from the McGovern Study.

Despite its prior arguments that observational studies cannot prove causation, 3M paradoxically attacks the McGovern study based on the Jeans study, an observational study that does not even evaluate whether Bair Hugger increases the risk of deep joint infection ("DJI")—the injury at issue in this litigation. Instead, this study looked only at the effect of pre-surgical MSSA screening and infection rates in general—lumping together DJI and wound infections. Absent from the Jeans study was any discussion, much less conclusion, that its findings disproved or called into question the alarming results of the McGovern study. In fact, in a more recent study, co-author Dr. Reed stated—without citing his work in Jeans—that Bair Hugger is a substantial contributor to laminar airflow disruption and is associated with substantially higher rates of DJI. These facts alone defeat 3M's motion. And even if the Jeans study had any relevance, 3M's own epidemiologist recently testified

that the study suffers from several serious limitations that ultimately preclude 3M from arguing that the study "confirms" that MSSA screening confounded the McGovern study.

The 2018 ICM Does Not Bar Plaintiffs' Experts' General Causation Opinions.

Likewise, 3M attempts to replow old ground by arguing that the 2018 ICM presents "compelling circumstances" to reconsider general causation. 3M made the same claim about the 2013 ICM in its first *Daubert* motion. This time, 3M's argument carries even less weight because the 2018 ICM backs off its finding that *no* studies show Bair Hugger increases the risk of DJI; it now concludes there is no *definitive* link but recognizes the theoretical risk. In essence, 3M asks the Court to impose a standard for admissibility that *Daubert* forbids, requiring experts to base their opinions on definitive scientific evidence.

Interlocutory Certification Is Inappropriate Based on 3M's Own Argument.

Finally, 3M lacks any legal basis to seek certification under 28 U.S.C. § 1292(b). In fact, 3M's own argument dooms its position. The Eighth Circuit's prior panel rule requires both this Court and the Eighth Circuit to apply the admissibility standard that this Court correctly cited in its initial *Daubert* decision, not the purported new standard in *Glastetter*.

LEGAL STANDARD

The Federal Rules of Evidence relax traditional barriers to opinion testimony and favor admissibility. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587–88 (1993). Expert testimony is admissible under Rule 702 if the reasoning or methodology underlying it is scientifically valid (reliable), and the reasoning or methodology can be applied to the facts at issue (relevant). *Id.* at 593. Scientific evidence is reliable if it is based on scientific methods. *Id.* at 590. The focus is on scientific principles, not conclusions. *Id.* at 595–96.

Because experts often reasonably differ when analyzing scientific issues, the Supreme Court has instructed that the **jury should resolve conflicting opinion testimony**. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999); *see also Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 564 (8th Cir. 2014) (declaring that "the jury, not the trial court, should be the one to decide among the conflicting views of different experts").

The Eighth Circuit has long adhered to the liberal standards of *Daubert* and Rule 702. The "exclusion of an expert's opinion is proper only if it is so fundamentally unsupported that it can offer no assistance to the jury." *Wood v. 3M Co.*, 112 F.3d 306, 309 (8th Cir. 1997). Proponents of expert testimony need not prove that the conclusions are correct, *Kuhn v. Wyeth*, 686 F.3d 618, 625 (8th Cir. 2012), and courts must not determine which of several theories has the best provenance. *Id.* at 633. It is an **abuse of discretion** to resolve doubts in favor of excluding expert testimony. *E.g.*, *Johnson*, 754 F.3d at 562.

The general rule is that "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *Hose v. Chicago Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995). Flaws in an expert's methodology, or the novelty of scientific conclusions, do not warrant exclusion of expert testimony. *Bonner v. ISP Techs. Inc.*, 259 F.3d 924, 929 (8th Cir. 2001). Such limitations go to the **weight of the testimony**. *Hose*, 70 F.3d at 974. Ultimately, as long as expert testimony rests on "good grounds, based on what is known," all disputes fall to the jury: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 590, 596.

ARGUMENT

I. 3M IMPROPERLY TRANSFORMS EVIDENTIARY RULINGS IN ONE CASE INTO SUBSTANTIVE RULINGS LIMITING THE ENTIRE MDL

3M's motion rises and ultimately falls on this argument: Plaintiffs are limited to their airflow disruption theory, says 3M, because *Gareis* prohibits them from asserting that Bair Hugger causes DJI based on the device's internal contamination. Defs.' Mem. at 7–8 ("[T]he Court may now focus on the airflow disruption theory as Plaintiffs' medical experts' **only basis** for attributing the association found in the Observational Study to the Bair Hugger."). However, evidentiary rulings in *Gareis* do not apply to other cases, much less general causation. Look no further than *Axline*—the second bellwether. There, the Court expressly ruled that "*Axline* is a **separate case** and **rulings from *Gareis* do not bind the Court here**," thus rejecting the same false premise underlying 3M's motion for reconsideration. *Axline v. 3M*, No. 17-cv-00511-JNE-DTS, Dkt. 42 at *9 (emphasis added).

The Court correctly refused to apply its evidentiary rulings from one bellwether to another—let alone to the entire MDL. *See, e.g.*, *In re Pinnacle Hip Implant Prods. Liab. Litig.*, 2016 WL 10707019, at *4 (N.D. Tex. July 5, 2016). Absent an order in the master docket, Pretrial Order 1 ¶6 makes clear that *Gareis* does not control the MDL. *See also In re Welding Fume Prods. Liab. Litig.*, 2010 WL 7699456, at *65 (N.D. Ohio June 4, 2010) (adjudicating motions *in limine* based on prior rulings because district court had issued a general order expressly declaring "these rulings will apply to all future cases in the MDL").

3M alternatively contends that the "logic" of *Gareis* "carries across the MDL because the Court's analysis was not limited to and did not depend upon the case-specific

facts in *Gareis*." Defs.' Mem. at 7. But neither logic nor science supports this argument. Far from it, as logic dictates that the *in limine* order depended on case-specific evidence.

The *Gareis* order does not mention the Court's general causation rulings or the general causation reports of Drs. Jarvis, Samet, or Stonnington, all of which state that Bair Hugger causes DJI through two causal mechanisms, not one. PX1 (Jarvis Rpt. at 8–25); PX2 (Samet Rpt. at 14–21); PX3 (Stonnington Rpt. at 5–6). The order instead relies on Dr. Jarvis's **case-specific** report. *Gareis v. 3M*, No. 16-cv-04187-JNE-DTS, Dkt. 306 at *1–3. But that report, unlike Dr. Jarvis's general report, does not opine that "Bair Hugger FAWs exhaust [ ] contaminated air into the OR/sterile surgical field through the exhaust hose **and the blanket**." PX1 (Jarvis Rpt. at 13) (emphasis added); *id.* at 12 ("[T]here are data to visually illustrate that the Bair Hugger FAW blankets are not secondary filters of the exhausted air."). Nor does the *in limine* ruling in *Gareis* acknowledge 3M's corporate testimony, numerous publications, and a bevy of internal documents confirming Plaintiffs' theory of internal contamination. *See* PX4 (30(b)(6) Dep. at 27:17–19) ("[T]here [is] no reason to blow particulates into [the] blanket, which might end up leaving the blanket.").[1]

[1] *See also* PX1 (Jarvis Rpt. at 12) (discussing Bernards' finding linking bacteria from Bair Hugger to DJI); *id.* at 9 (discussing Albrecht 2009's conclusion that Bair Hugger "blow[s] a large number of particles into the sterile field"); *id.* at 10 (discussing Albrecht 2011's conclusion that Bair Hugger emits "contaminants into the operating room"); *id.* (discussing Reed's conclusion that Bair Hugger should be upgraded to "reduce contamination buildup and emission risks"); *id.* at 12 (discussing Wood, which states "FAW does contaminate ultra-clean air ventilation" based on studies regarding "direct contamination of air that blows from the forced-air machines"); PX5 (Baker at 153–54) (finding "insufficient evidence to justify the routine use of forced air warming units as an intraoperative measure during ultraclean orthopaedic surgery" because "the blanket is not designed to act as a microbial filter"); PX6 (Beavers at 3) ("Previous outbreaks have found items such as . . . Bair Hugger . . . to be reservoirs of infection."); PX7 (Gjolaj) ("[A] potential disadvantage

More important, the *Gareis* order excluded Plaintiffs' "second theory" of causation because "[n]o examination was conducted of the Bair Hugger that was used in the surgery **Mr. Gareis** claims caused his infection." *Gareis*, Dkt. 306 at *2–3. The Court's analysis is therefore limited to one case, whereas in future cases Plaintiffs may conduct such an examination just as Bernards et al. did in implicating Bair Hugger in an outbreak of a deadly pathogen.[2] PX14 (Bernards 2004); *cf.* PX15 (Sax 2015) (same for heater-cooler).

Finally, even assuming *arguendo* that the "logic" of *Gareis* applies to general causation, the order does not address the fact that Bair Hugger pollutes operating rooms regardless of the "business end" of the device. Droves of documents show that Bair Hugger was [redacted] PX2 (Samet Rpt. Ex. C at 11) (citing 3MBH000045482). Thus, even if case-specific reports in *Gareis* did not show "any pathogen coming out of the 'business end' of

is that the BH may blow contaminated air."); PX8 (ECRI 2017 at 3) ("A warming unit should have HEPA-grade or better air filters to reduce the risk that airborne dust, bacteria, and mold will be blown onto the patient or into wounds."); PX9 (3MBH01617180) [redacted]; PX10 (3MBH00529150) ([redacted] PX11 (McGovern Dep. II at 286:20–24) (stating bacteria "could pass through the blanket").

[2] That is only possible, of course, if 3M does not lose track of its dirty "vacuum" or prohibit access to the device. PX12 (3MBH01260231) ([redacted]; PX13 (3MBH02087968) [redacted]).

the Bair Hugger," **it still emits bacteria**. PX4 (30(b)(6) Dep. at 317:10–19) (3M has not "conducted any internal testing" to show the "blanket itself may act as an additional filter").

At bottom, 3M's motion rests on a one-legged stool that topples on the false premise that an evidentiary ruling in one case reversed this Court's *Daubert* ruling *sub silentio*. Because the case-specific order in *Gareis* excluding evidence of Plaintiffs' contamination theory neither binds nor applies to thousands of other cases in this MDL, the motion fails.

II. DR. ELGHOBASHI'S REPORT AND TRIAL TESTIMONY CONFIRMED EARLIER PUBLISHED STUDIES SHOWING THAT BAIR HUGGER DISRUPTS AIRFLOW AND CONTAMINATES THE STERILE FIELD

3M also engages in a game of semantics. Attacking the terminology Plaintiffs and their experts used to describe to the jury how ultra-clean hospital ventilation systems work, 3M misleadingly claims that Dr. Elghobashi repudiated Plaintiffs' so-called "force field" theory of causation. This argument is spurious and ultimately elevates form over substance.

"Laminar" or "unidirectional" airflow are umbrella terms commonly used in the medical community to describe airflow systems in operating rooms, which are designed to blow cool, sterile air downward over the sterile field. For example, Mosby's Medical Dictionary defines "laminar air flow" as "a system of circulating filtered air in parallel-flowing planes in hospitals or other health care facilities. The system reduces the risk of airborne contamination and exposure to chemical pollutants in surgical theaters." PX16.

Dr. Presnal, the treating orthopedic surgeon in *Gareis*, similarly described "laminar" airflow as a catchword for unidirectional flow from the ceiling of the operating room to the floor. PX17 (Presnal Dep. at 147:16–21). He testified that OR ventilation systems are designed to be "top down so that it's not pulling up things from the ground, so it's always

pushing things down towards the floor." *Id.* at 17:18–22. The purpose of these systems is to push particles containing contaminants away from the operative field. *Id.* at 148:14–16.

Analogizing this design to a "force field," Dr. Stonnington, Plaintiffs' orthopedic expert, likewise explained the effect of "laminar" or "unidirectional" ventilation as follows:

> This is – up here are the diffusion panels where . . . clean air is being pushed through into the operating room. And it pushes those falling skin cells, and lint, and dust, and everything that we don't like on our patients down and out, so away. It's basically creating this force field that the patient is in, and all that stuff is being exhausted to the returns or the exhaust fans in the room.

PX18 (TT at 366:13–20).[3]

3M takes the term "force field" out of context. The "force field" is not, as 3M suggests, a concept invented by Plaintiffs or their experts. Both Plaintiffs' and 3M's experts recognize that the goal of operating room airflow—whether called "laminar," "unidirectional," or "turbulent"—is to protect patients by sweeping airborne particles below and away from the sterile field. 3M's HVAC expert, Michael Keen, declared that the purpose of laminar or unidirectional airflow is "to have the air supplied from the center of the [operating] room over the top of the patient and the operating room table over the staff that are there and washed away to the outsides and then exhausted from the corners." PX18 (TT at 1580:9–16). Though he did not use the term "force field," Keen opined that "the laminar flow characteristic in an operating room is an important design feature to provide a **protective field** from infiltration of possible contamination." *Id.* at 1641:2–16.

[3] 3M asserts that Dr. Jarvis also testified about a "force field." Defs.' Mem. at 10. He did not. The trial testimony that 3M quotes is Dr. Stonnington's. PX18 (TT at 512:12-513:4).

In essence, 3M's attack on the "force field" analogy boils down to a quibble over semantics. As explained below, the words "laminar" and "unidirectional," as used by physicians and study authors to describe the design of the ventilation system to maintain a sterile field, does not in any way undermine Plaintiffs' airflow disruption theory. To the contrary, multiple published studies conclude that hot air expelled by Bair Hugger disrupts ventilation airflow, thereby moving potentially bacteria-laden particles into the sterile field.

A. Dr. Elghobashi's Criticism of the Word "Laminar" Does Not Disprove Plaintiffs' Airflow Disruption Theory of General Causation

Dr. Elghobashi has repeatedly criticized the term "laminar" as it is generally used in the medical literature and by medical professionals to describe ultra-clean ventilation airflow in operating rooms because it is technically inaccurate to an engineer. By definition, "laminar" flow occurs at a lower velocity (below 2000 Reynolds number). PX19 (Elghobashi 750 Rpt. at 5 n.1). As Elghobashi explained in his general causation report:

> Based on the standard values of air exchanges per hour (ACH) for an OR (25 per hour) . . . the flow Reynolds numbers are much larger than 2000, a critical value beyond which turbulence occurs in a duct. . . . Although the level of turbulence in the inlet flow is not large (< 10%), the flow contains velocity fluctuations, and is unsteady.

Id.

As a preeminent expert in the field of CFD, Elghobashi was understandably critical of the imprecise and overly simplistic way researchers use the terms "laminar" and "unidirectional" in characterizing airflow. However, the fact that the ultra-clean airflow in operating rooms is "turbulent," not technically "laminar," as that term is understood by some engineers, is **irrelevant** to the conclusions Elghobashi reached in his investigation.

Elghobashi conducted large-eddy simulations ("LES") on the Bair Hugger models 750 and 505 to study the interaction of operating room ultra-clean air velocity airflow with the flow created by Bair Hugger's exhaust and the effect of this interaction on the dispersion of squame-sized particles in an operating room. He performed separate simulations changing only whether Bair Hugger was turned off or on warm. His LES showed that when the blower was off, "the ventilation air from the ceiling inlet grilles moves downwards, then is deflected by the surgical lights and the [operating table], impinges on the floor farther away from the OT, and finally exits through the outlet grilles" on the walls of the operating room. PX19 (Elghobashi 750 Rpt. at 61). Buoyant thermal plumes from the warm surfaces of the surgical staffs' heads, the patient's head and knee, and the surgical lamp were "relatively weak and do not significantly alter the mean ventilation airflow." *Id.* Most squames were "dispersed by the ventilation air flow towards the outlet grilles. None of [them] actually rise to the level of the side tables or the OT." *Id.*

In contrast, with the Bair Hugger turned on, the turbulence created by the hot air from the machine created thermal plumes rising from underneath the OT upward, reaching the ceiling in some places. *Id.* A "large number of squames are lifted upwards by the rising thermal plumes. Some of the squames are lifted above the surgeons' heads and are blown towards the OT by the downward moving ventilation air" and "very close to the patient's knee and surgical site." *Id.* at 61–62; *see also* PX20 (Elghobashi 505 Rpt. at 15–16).

These findings do not deracinate Plaintiffs' premise that operating room ventilation systems protect the sterile field from airborne contamination. Quite the opposite, as

Elghobashi's study showed that without Bair Hugger running, the standard operating room ventilation system disperses squames away from the sterile field, as it was designed to do.

Elghobashi's published LES also coheres with other published studies, which used different methods to measure the effect of Bair Hugger on operating room airflow during orthopedic procedures. Each of those peer-reviewed studies found that the convection currents produced by Bair Hugger significantly increased the number of particles by drawing them from below the operating table into the sterile field.[4] Even 3M concedes that **every study shows that Bair Hugger increases the number of particles over the sterile field**, and there are **no studies to the contrary**. PX18 (TT at 176:20-177:18). Through his LES simulation, Elghobashi used a three-dimensional model to calculate the dispersion of particles in the operating room setting with far more precision than prior studies. His LES provides confirming scientific evidence that Bair Hugger disrupts operating room airflow and ultimately causes potentially bacteria-laden particles to travel into the sterile field.

3M's specious assertion that Elghobashi's disparagement of the words "laminar," "unidirectional," and "force field" undermines Plaintiffs' airflow disruption theory is also untimely. Elghobashi's position on airflow is neither new nor controversial. 3M was aware of Elghobashi's opinions about the misuse of the word "laminar" when he first served his general causation report in **March 2017**. That report unambiguously stated that the medical literature incorrectly characterizes ultra-clean airflow in operating rooms as "laminar" instead of "turbulent." PX19 (Elghobashi 750 Rpt. at 5 n.1). Elghobashi echoed that view

[4] PX21 (Legg); PX22 (Legg & Hamer); PX23 (Belani); PX24 (Dasari); PX25 (McGovern).

in his **2017 deposition**. PX26 (Elghobashi 2017 Dep. at 265:20-266:24). And in his **2018 deposition**, Elghobashi reiterated that operating room airflow is not laminar, which defense counsel acknowledged he now understood. PX27 (Elghobashi 2018 Dep. at 200:14-201:5).

Had Elghobashi's opinion actually vitiated Plaintiffs' mechanism theory and the peer-reviewed studies that support it, 3M surely would have made it the centerpiece of its initial *Daubert* motion. But it did not. There is nothing new in the record, including the *Gareis* trial, that changes the foundation of evidence the Court already considered in denying 3M's motions to exclude Plaintiffs' general causation opinions. 3M cannot now feign surprise over Elghobashi's trial testimony and pretend it is "new evidence" warranting reconsideration of this Court's *Daubert* decision, especially since **3M's argument flies in the face of its own expert testimony**. PX28 (Abraham *Trombley* Rpt. at 1 n.1) ("As Dr. Elghobashi and others have commented, airflow in an operating room cannot be truly 'laminar,' [so] [w]hen I use the term 'laminar' in this report . . . I am merely repeating it as a descriptive term that appears in the literature on operating room airflow.").

B. The Fact that Dr. Elghobashi's CFD Did Not Calculate Every Possible Variable Affecting Airflow Does Not Make His Testimony Unreliable

3M also argues that Elghobashi's CFD model is unreliable because he did not calculate all of the possible airflow variables that exist in a realistic operating room setting, claiming he admitted that other sources of heat and turbulence would have enhanced the spreading of squames. Defs.' Mem. at 13. This grossly mischaracterizes Elghobashi's trial testimony and methodology. These additional variables, if measured, would have

exacerbated, not mitigated, the dangerous effect of Bair Hugger by spreading even more squames blown upward from the floor—a point Elghobashi repeatedly emphasized at trial.

Nor is Elghobashi's LES simulation any less "realistic" than those of other researchers, **including 3M's own expert**, in evaluating the deleterious effect of Bair Hugger. None of the other airflow studies accounted for all of the variables 3M now claims are missing. *See, e.g.*, PX18 (TT at 177:19–180:21) (Van Duren admitting 3M's test did not "replicate an actual operating room" and still showed "an effect on unidirectional airflow"). Elghobashi's simulation, which was peer-reviewed and published in a reputable scientific journal, "meets at least the minimal criteria of good science" under *Daubert* and Rule 702. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995).

Elghobashi focused his LES specifically on Bair Hugger's effect on the movement of particles in the turbulent airflow in an operating room. PX18 (TT at 880:3–6). His LES modeled a real operating room, prepped and equipped in the exact manner, with the same contents, as a realistic total knee arthroplasty. Real people—not mannequins as in the Sessler study that 3M sponsored—were used as the patient and surgical team. PX18 (TT at 878:17-880:2); *cf.* PX29 (Sessler 2011). Elghobashi's role as a general causation expert was not to perform a different CFD calculation on every conceivable configuration or to account for every random movement. Such an undertaking would be practically and theoretically impossible. Nor has 3M conducted such a study. Rather, [redacted]. PX30 (3MBH00580785–89) ([redacted]

Elghobashi has repeatedly explained that he set up his LES as conservatively as possible. His purpose was to model the "best case scenario" for 3M by eliminating other sources of airflow disruption that would only magnify Bair Hugger's impact. He conservatively selected a modest number of squames and positioned them near the floor instead of throughout the operating room to avoid overestimating the effect of Bair Hugger. PX18 (TT at 881:8–13); PX26 (Elghobashi 2017 Dep. at 166:23-167:10). He also modeled his operating room with four outlet grilles near the floor instead of higher on the wall since outlets at higher elevations would enhance Bair Hugger's impact on disbursing squames toward the table—another "best case scenario" for 3M. PX18 (TT at 950:10-23, 951:5-13).

Just like 3M's CFD expert Dr. Abraham, Elghobashi did not model the effects of doors opening and closing and people going in and out of the operating room because it would have exacerbated the Bair Hugger's alarming effects. PX28 (Abraham *Trombley* Rpt. at 19). Elghobashi described this reasoning in his 2017 general causation report: "If these squames are lifted by the turbulent air and moved to the surgical site, other effects such as motion of medical equipment and staff, additional squames shed from the heads and faces of medical staff, surgical garments, etc. will have an **even higher probability** to reach the surgical site." PX19 (Elghobashi 750 Rpt. at 42). It is simply good scientific methodology to isolate the effect of the agent being studied. As Elghobashi explained, "I repeat again. If we allowed the people to move and the doors to open and close, the Bair Hugger effect would have been enhanced in spreading squames. So we did it such that just to isolate the effect of Bair Hugger, that's how we do science." PX18 (TT at 963:1–5).

Researchers in other Bair Hugger airflow experiments followed the same scientific methodology, **including 3M's CFD expert Dr. Abraham**. PX28 (Abraham *Trombley* Rpt. at 19). For example, in the Belani study, which used bubbles to investigate Bair Hugger's effect on operating room airflow, Dr. McGovern explained why he and his colleagues did not perform their simulation with staff moving around and operating different equipment:

> [T]hat's not what we collected data on, because people moving around the room is not – is a variable you can't control for. So we wouldn't know if a particular result was because someone had walked through the laminar flow zone at this time, or if it was controlled. **So in an experimental study, it was important to keep things as consistent as possible so the results were as valid as possible.**

PX31 (McGovern Dep. I at 218:17-219:12).

Dr. Legg agreed that it is important to keep measurements consistent "[b]ecause we wanted to find out one thing and that is the effect of the warming device and if we changed other parameters it could have resulted in a misleading outcome." PX32 (Legg Dep. at 107:17–24). Dr. Belani likewise testified that the simulation he performed at the University of Minnesota did not have people moving in the operating room, as that was not what they were testing. PX33 (Belani Dep. at 114:21-115:11). No staff were present "because that might have actually made it **worse** [with] more bubbles going to the surgical field." *Id.* at 110:9–18. Notably, **none** of the particle studies—including 3M's—have measured the effect, if any, of opening and closing doors and people moving around the operating room.[5]

[5] A new study, however, has found that door openings are not significantly associated with increased colony-forming units in laminar flow operating rooms. *See* PX34 (Perez 2018).

Elghobashi did not, as 3M claims, ignore the role of other sources of heat and air movement such as computers, electrocautery devices, and surgical saws. In addressing these sources, Elghobashi focused on the variables that mattered. PX26 (Elghobashi 2017 Dep. at 206:4-207:9). Computers, electrocautery devices, and anesthesia machines, for example, release a low amount of wattage that do not increase heat or movement enough to have a significant effect on airflow disruption. PX18 (TT at 893:4-895:2). Even 3M's experts agree that anesthesia machines, surgical lights, computer monitors, computer consoles, electrocautery devices, bovie machines, and the hand movements of surgeons **do not significantly increase airborne contamination in operating rooms**. PX35 (Wenzel Dep. at 99:4-104:2). Ultimately, 3M asks the Court to foist upon Plaintiffs' experts a methodology that neither the relevant scientific community nor 3M's own experts follow.

For example, 3M takes the diametrically opposite position when presenting Abraham's CFD. Unlike Elghobashi, Abraham did not compare Bair Hugger turned off versus on. PX18 (TT at 1851:24-1852:1). Abraham did not model any doors opening or closing. *Id.* at 1861:10–12. And he did not model any people moving around in the operating room. *Id.* at 1861:13–15. In fact, although he claimed that "everything" would affect operating room airflow, *id.* at 1861:9, Abraham did not include the heat from a bovie, anesthesia machine, or personal computers in his CFD. *Id.* at 1862:9–12. Yet he stood by his results. *Id.* at 1713:17–23. It is duplicitous for 3M to impose a more demanding standard on Plaintiffs' expert testimony. *Thomas v. Evenflo Co.*, 2005 WL 6133409, at *3 (N.D. Ala. Aug. 11, 2005) (stating the standards for admitting expert testimony apply with equal force to all experts, "whether the proponent is the plaintiff or the defendant in a civil suit").

By demanding a standard of absolute perfection to the admissibility of Plaintiffs' expert testimony, 3M invites the Court to abuse its discretion. Neither Rule 702 nor *Daubert* requires experts to base their opinions to a scientific absolute. *Bonner*, 259 F.3d at 929. The Eighth Circuit has consistently cautioned that the factual basis of an expert opinion goes to **credibility, not admissibility**. *Id.* As long as the methods employed by the expert are scientifically valid, "mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony." *Hill v. Sw. Energy Co.*, 858 F.3d 481, 486 (8th Cir. 2017). Even crude and imperfect calculations may still be helpful to the jury. *Id.* In fact, expert opinions are not rendered inadmissible even if an underlying assumption is called into doubt. *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 615 (8th Cir. 2011); *see also id.* at 614 (citing *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1345 (11th Cir. 2003) (concluding that testimony of expert who used wrong information in his CFD analysis was still reliable and would be helpful to the jury)).

Finally, reverting to its "force field" mantra to claim this term stands for something other than protective airflow, 3M insists that Plaintiffs' airflow disruption theory is irrelevant because Elghobashi's study does not prove what Plaintiffs say it does. This argument is both circular and false. Elghobashi's LES found that with Bair Hugger off, the HVAC system did what it intended to do, pushing air down and away from the sterile field. PX19 (Elghobashi 2017 Rpt. at 61). The airflow, in effect, protected the patient with a "force field" of clean air as Dr. Stonnington put it. With the blower on, Bair Hugger significantly increased turbulence underneath and around the operating table, with plumes from the device lifting squames over the surgical field and near the wound. *Id.* at 61–62.

Belani obtained similar results in his particle study, concluding that "[e]xcess heat from forced air warming resulted in the disruption of ventilation airflows over the surgical site." PX23 (Belani 2013 at 406). Dasari likewise concluded that "forced-air warming generates convection current activity in the vicinity of the surgical site. The clinical concern is that these currents may disrupt ventilation airflows intended to clear airborne contaminants from the surgical site." PX24 (Dasari 2012 at 244). And Legg concluded that Bair Hugger created convection currents that rose against the downward airflow and increased particle concentration **"1000-fold"** by drawing potentially contaminated particles from below the operating table into the surgical site. PX22 (Legg 2013 at 407).

Elghobashi's research, combined with other mechanistic studies, is undeniably relevant to Plaintiffs' airflow disruption theory. Not only is Elghobashi's LES simulation "appropriate in the circumstances" of this case, but it "actually proves what [Plaintiffs] claim it proves." *See Shuck v. CNH Am., LLC*, 498 F.3d 868, 875 n. 3 (8th Cir. 2007).

The cases that 3M cites are easily distinguished. In *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016), the court excluded the testimony of plaintiff's engineer because his study of IUD failure did not reliably replicate the conditions inside a woman's uterus, based on his use of double-sided tape to affix the IUD's arms to a block to apply pressure to the device and hold it in place. *Id.* at 441–42. In *Weinbarger v. Bos. Sci. Corp.*, 2015 WL 1887222 (S.D. W. Va. Apr. 24, 2005), the court barred the testimony of a chemistry expert because his experiment, which he designed to replicate the degradation effects of transvaginal mesh, was conducted in temperatures over 200 degrees Celsius, well over human body temperatures. The expert did not explain how the same

effect would occur at lower temperatures. *Id.* at *17. These cases are a far cry from Elghobashi's CFD, a controlled experiment using a model operating room, under the same conditions as a joint replacement surgery—essentially the same setup 3M's experts used in their own CFD. Elghobashi's study was also sufficiently reliable and relevant to be published in a peer-reviewed journal, as were similar particle studies. *See* PX36 (He 2018).

Bland v. Verizon Wireless, 2007 WL 681791 (S.D. Iowa Aug. 9, 2007), likewise has no application here. That case excluded the differential diagnosis of plaintiff's physician because she relied only on temporal relationship between exposure and injury and provided no data to support the dose threshold at which Freon could have caused the plaintiff's asthma; nor did she address other potential causes. Elghobashi is a general causation expert; he did not perform a differential diagnosis. His CFD directly addresses the precise mechanism by which Bair Hugger can cause bacteria-laden particles to travel to the patient.

Further, in *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288 (M.D. Fla. 2007), the court barred the plaintiff's causation expert's testimony because the animal studies he relied on involved higher doses of substances than those administered to humans and did not show that Accutane could cause inflammatory bowel disease. *Id.* at 1289, 1294–96. And in *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316 (7th Cir. 1996), the expert was excluded because he cited no evidence showing that use of a nicotine patch caused heart attacks. The expert's opinion was therefore based on no more than "scientific guesswork." *Id.* at 319.

None of these evidentiary chasms exist here. Elghobashi's testimony helps the jury understand the mechanism by which Bair Hugger is dangerous. The results of his CFD are also coherent with other studies, all of which show Bair Hugger increases particles over

the surgical field. Under binding precedent, any failure of Elghobashi (and Abraham) to account for every conceivable variable is a matter of **weight, not admissibility**. *Lauzon v. Senco*, 270 F.3d 681, 693 (8th Cir. 2001); *Johnson*, 754 F.3d at 563 (failure to rule out possible causes is not a valid basis to exclude testimony); *Hill*, 858 F.3d at 486 (mere disagreement with assumptions does not warrant exclusion of testimony). And even if there were any reason to elevate form over substance, as 3M urges, the Court cannot take sides. *Lauzon*, 270 F.3d at 695 (explaining that even where "there exists a close case on relevancy of the expert testimony in light of the plaintiff's testimony to allow the expert opinion and if the court remains unconvinced, [it is better to] allow the jury to pass on the evidence").

C. 3M Distorts the Findings of Dr. Elghobashi's CFD, which Shows Squames Above the Surgical Site as well as Above and Near the Wound

In designing his LES of Bair Hugger 505—the model used in Mr. Gareis' surgery—Elghobashi ran his study for 45 seconds with the device turned on. The duration of a total knee or hip arthroplasty is at least an hour. But given the complexity of three-dimensional LES calculations, it is unfeasible and cost-prohibitive to conduct a one-hour simulation. PX19 (Elghobashi 750 Rpt. at 16). The 45-second calculation that Elghobashi performed required **400 hours** of **super-computer** processing time. PX20 (Elghobashi 505 Rpt. at 2).

The simulation shows that thermal plumes from Bair Hugger caused a significant number of squames to be lifted above the operating table, then blown down toward the surgical site by the ventilation air. *Id.* at 3, 15. **Figure 7** specifically shows that "[s]everal particles are still suspended above the OT and are being transported downwards by the ventilation air and may potentially reach close to the surgical site." *Id.* at 3, 10. With Bair

Hugger off, however, none of the squames rose above the operating table. *Id.* at 15. The results were "very similar" to the model 750 simulation, except that it took slightly longer for squames to move above the surgical site in light of the 505's lower flow rate. *Id.* at 3.

Nevertheless, 3M maintains that Elghobashi's study is irrelevant because the 45-second video does not show any particles landing on the knee. This argument is myopic for the obvious reason that the simulation depicted **only 45 seconds of a one-plus hour surgery**. Over the course of the entire procedure, the Bair Hugger will continue to blow squames above the operating table, and the ventilation airflow will continuously force the squames down in the immediate vicinity of the wound site and instrument tables. Indeed, because Elghobashi's LES shows that a **statistically significant** number of squames are transported to the sterile filed, it is more probable than not that some of these squames will land on the knee or hip joint during the one-plus hour procedure. *See, e.g.*, PX36 (He 2018).

3M nonetheless surmises that heat plumes emanating from the patient's body and knee will keep the squames suspended in the air, creating a so-called "wound plumb" with a "protective effect" that blocks particles from getting inside the incision. For its own "force field" theory, 3M relies on early studies by Memarzadeh reported in 2002 and 2003.[6] However, Elghobashi debunked these experiments in both his report and published paper.

First, Memarzadeh's studies did not consider Bair Hugger's discharge. PX19 (Elghobashi 750 Rpt. at 5). *Second*, Memarzadeh's studies used RANS, an antediluvian model that cannot compute the instantaneous velocity field, which is required to accurately

[6] Like Dr. Elghobashi, Memarzadeh analyzed whether Bair Hugger impacted the trajectory of particles, not bacteria, in operating rooms. So too did the Sessler study funded by 3M.

calculate the forces on particles and particle trajectories. *Id.* Under RANS, "only the mean velocity field that varies in space is obtained, and all information about the time-dependent fluctuations of the velocity field around the mean flow is lost." *Id.* at 14. *Third*, because RANS and its constants "are not universal, using them for a complex flow such as air circulation in an operating room invariably provides inaccurate results. Experimental data is necessary to adjust the model constants and thus the RANS models are not predictive." *Id.* Thus, unlike Elghobashi's LES, Memarzadeh's RANS cannot predict the locations of squames at any particular time in the operating room; nor can it conclude that particles will not penetrate the thermal plume. *Id.* at 5. Even if his assumption were true, **Memarzadeh still found that 2% to 5% of particles reached the surgical site**. *See, e.g., id.* Because a small inoculum of bacteria can cause DJI, *see, e.g.*, PX37 (Lidwell 1983), Memarzadeh's studies actually support Plaintiffs' airflow disruption theory. PX1 (Jarvis Rpt. at 16–17).

3M's "wound plumb force field" theory is also incompatible with more recent studies on airborne particulates and DJI, which demonstrate that contaminated airborne particles do, in fact, reach the wound site. Darouiche at al. conducted a randomized clinical trial—the first of its kind—to investigate the relationship between DJI and levels of airborne bacteria ("CFU") near incision sites during total joint replacement surgeries. PX38 (Darouiche 2017). The randomized trial showed that airborne CFU entering the incisions during surgery was a likely source of contamination leading to DJI, and that reducing CFU within the sterile field reduces the incidence of DJI. *Id.* at 6, 8. CFU density was also significantly related to total particulate density, indicating that **airborne particle counts may be used as a proxy for ambient CFU density** in orthopedic surgeries. *Id.* at 6. These

results confirmed the findings by Stocks et al. that: 1) particle counts provide a real-time proxy for increased risk of DJI during joint arthroplasty procedures; 2) airborne particulate contamination of the wound is a cause of post-operative DJI; and 3) controlling airflow environment may limit the number of airborne microbes. PX39 (Stocks 2010 at 202–03).

In sum, 3M's "wound plumb force field" theory is a feeble one and fails to undermine the relevance of Elghobashi's study. 3M is free to cross-examine Elghobashi and Plaintiffs' other experts about Memarzadeh's studies, as they did in *Gareis*. Blackletter law makes clear, however, that exclusion of Elghobashi's testimony is unwarranted here.

D. Other Published and Peer-Reviewed Studies Reliably Support the Well-Established Fact that Bair Hugger Disrupts Operating Room Airflow

As they did with Elghobashi, 3M attempts to decry various particle studies because they do not replicate "realistic" conditions. 3M also claims that Plaintiffs' experts never testified that these published and peer-reviewed studies, standing alone, support causation. These arguments woefully mischaracterize the basis of Plaintiffs' experts' testimony and the standard methodology that scientists routinely use to infer causation. In doing so, 3M ultimately asks this Court to impose a pseudo-scientific standard for the admissibility of general causation testimony, which both *Daubert* as well as Rules 702 and 703 forbid.

At the outset, 3M overlooks the focus of the particle studies. By attacking them for using mannequins instead of human patients, 3M ignores that these experiments were not designed to investigate whether particles infected the patient. Their intent was to compare the effect of Bair Hugger versus controls on heat and airflow disruption in the vicinity of

the operative site. In each study, the mannequin was positioned, clad, and draped the same way as a patient in a real surgery. *See, e.g.*, PX11 (McGovern Dep. Vol. II at 293:9–294:3).

In denouncing the studies for failing to test "real world" variables, 3M also turns a blind eye to standard surgical protocols. The medical community has long known that too much motion or activity in the OR disrupts the airflow and increases infection risk, which is why hospitals go to great lengths to minimize the number of staff and movement in the OR—especially in orthopedic implant surgeries. PX1 (Jarvis Rpt. at 16) (citing CDC HICPAC Recommendations); PX17 (Presnal Dep. at 15:23-16:21) (describing measures to limit movement in the OR). Movement is also not a constant variable. As Dr. McGovern pointed out, it is a random event, and a well-designed study cannot account for such variables. PX31 (McGovern Dep. Vol. I at 218:17-219:12); PX32 (Legg Dep. at 107:17–24); PX33 (Belani Dep. at 114:21-115:11). Not to mention that movement by surgical staff would actually have made Bair Hugger's disruptive effects even worse. *Id.* at 110:9–18.

More important, **none of these perceived shortcomings prevented publication** of these studies. Had the use of mannequins, lack of "movement" comparisons, and other limitations made the studies unreliable, the peer-reviewers of these journals would never have accepted them for publication. *See, e.g.*, PX40 (Belani_00008) (responding to peer-reviewer's comments about setup). Nor do 3M's criticisms of these peer-reviewed studies affect their relevance to Plaintiffs' experts or their value to the medical community in toto. In their 2014 review article, Wood et al. examined these and other studies and concluded that the combined scientific evidence was convincing enough to urge surgeons to consider using other patient warming methods in hip and knee surgeries. PX41 (Wood 2014 at 7).

3M attempts to discredit these studies by pointing to the usual language that "further research is needed," even though the company shirked its duty to conduct such research and failed to warn of danger when other manufacturers of forced-air warming devices did.[7] *See, e.g., Mack v. Stryker Corp.*, 748 F.3d 845, 849–50 (8th Cir. 2014) (medical device manufacturers "have a duty to test and investigate their products based upon the foreseeable risk of harm to potential users in light of current medical knowledge and discoveries").

In any event, these cautionary statements are par for the course in scientific papers. The *Reference Manual* makes clear that this is not a concession of ignorance "but rather an expression that all scientific fields are open-ended and can progress from their present state." *Reference Manual* at 599 n.143; *see also Ambrosini v. Labarraque*, 101 F.3d 129, 138 (D.C. Cir. 1996) ("the fact that science would require more evidence before conclusively considering the causation question resolved" is not the appropriate standard).

Further, after the Wood article, more recent research fills any alleged gaps in the particle studies. Elghobashi's published LES shows how, in real time, Bair Hugger transports squames (40% of which carry bacteria per 3M's expert Dr. Wenzel) over the sterile field. PX18 (TT at 763:12–23). The randomized trial published by Darouiche also shows that in real-world arthroplasties an **increase in airborne particles increases CFU density** at the surgical site, which **increases the risk of DJI**. PX38 (Darouiche 2017). The totality of this evidence, plus epidemiologic data from the McGovern study, provides a sound scientific basis for Plaintiffs' experts to conclude that Bair Hugger causes DJI.

[7] *See, e.g.*, PX42 (David Rpt. at 41) (Stryker warning regarding "airborne contamination").

3M nevertheless insists that the five Bair Hugger particle studies, standing alone, fail to provide a reliable foundation for Plaintiffs' experts' opinions. This claim is not only anathema to how scientists reach inferences of causation; it is roundly rejected as inimical to *Daubert* and Rules 702 and 703. *See, e.g.*, *Milward v. Acuity Specialty Prods. Group, Inc.*, 639 F.3d 11, 23 (1st Cir. 2011) (court abused its discretion in reasoning that "because no one line of evidence supported a reliable inference of causation, an inference of causation based on the totality of the evidence was unreliable"); *U.S. v. W. R. Grace*, 504 F.3d 745, 762, 765 (9th Cir. 2007) (court abused its discretion in requiring that each source of evidence must independently support the expert's conclusion); *NutraSweet Co. v. X-L Eng'g Co.*, 227 F.3d 776, 789 (7th Cir. 2000) (expert's reliance on individual pieces of evidence, while insufficient in themselves to prove a point, was not grounds for exclusion).

Plaintiffs' experts did not base their opinions on a single study or a monolithic line of evidence, but on **all of these sources combined**. PX43 (Samet Dep. at 164:24-165:9, 224:11–19); PX18 (TT at 601:16–24, 629:9-631:10). This is the approach all scientists follow when making causal judgments. PX44 (Borak Dep. I at 67:24-68:3). Although experts commonly disagree on their interpretations of data, these disputes go to weight, not admissibility. *In re Celexa & Lexapro Prods. Liab. Litig.*, 927 F. Supp. 2d 758, 766 (E.D. Mo. 2013). 3M's renewed attacks on the reliability of Elghobashi's LES as well as other mechanistic evidence regarding airflow disruption are thus unworthy of reconsideration.

III. 3M'S ATTACK ON MCGOVERN DEFIES LOGIC, LAW, AND SCIENCE

Re-plowing old ground, 3M next challenges the McGovern study. This time, though, it does so with far less evidence and despite blackletter law, logic, and science.

A. The McGovern Study Is Independent Evidence of General Causation

3M predicates its attack on two deductions. First, it says, the "Court did not exclude the general causation testimony of Plaintiffs' medical experts because the association identified in [McGovern] was supported by the causation mechanism purportedly shown in Elghobashi's CFD." So, says 3M, if the "CFD does not show that the Bair Hugger causes [DJI] in real-world OR conditions," the Court should grant its motion. Defs.' Mem. at 23.

Syllogisms are venerable tools of logic, but their conclusions are only as good as their parts. As to 3M's first premise, the Court never ruled that Plaintiffs' experts could rely on McGovern only because Dr. Elghobashi's CFD supported it. The opposite is true.

While "Elghobashi's testimony is **sufficient** to support Samet's causal inference," the Court correctly recognized that Dr. Samet relied on "other" evidence and ultimately ruled: "And **anyway**, Samet need not rule out every alternative explanation for the observed hospital's drop-off in infections," as reported in McGovern. MDL Dkt. 1024 at *9. In addition, nary a word of the Court's *Daubert* order mentions any nexus between the causation opinions of Drs. Jarvis and Stonnington on the one hand, and Dr. Elghobashi on the other. And that's not all—the second premise is fatally flawed. *See supra* Section II(B).

B. The Published and Peer-Reviewed McGovern Study Is Relevant Evidence of General Causation Notwithstanding the Jeans Study

3M's second deduction fares no better. According to 3M, the McGovern study is not valid epidemiologic evidence in light of the recently published Jeans study, *see* Defs.' Mem. at 25–28; causal inference requires epidemiologic evidence, *see id.* at 24–25; ergo, the Court should grant the motion for reconsideration of general causation. *See id.* at 28.

1. The McGovern study remains a valid epidemiologic study.

The first premise of 3M's syllogism is wrong for a simple reason: the McGovern paper is a valid epidemiologic study. It is a published, peer-reviewed observational analysis that found a positive association between Bair Hugger and DJI. *See, e.g.*, *Daubert*, 43 F.3d at 1318 (publication in a peer-reviewed journal shows the study "meets at least the minimal criteria of good science"). Specifically, the McGovern study reported a **statistically significant 3.8-fold increased risk** of DJI from Bair Hugger compared to air-free devices.

As is routinely done in scientific papers, the well-credentialed authors described the methods they used and their findings.[8] The study grew out of pre-litigation research, passed peer review, and was published in a respected medical journal; it has never been retracted. Nor has anyone in the scientific community called for its retraction. All of the McGovern authors, moreover, were deposed as part of this litigation and each testified under oath that they stand behind the published study.[9] The scientists who peer reviewed the study also assert that it "demonstrates that there were **actual changes in infection rates** which would **fit well with the experimental data** and therefore support the contention that there is a **serious issue** to be addressed with [Bair Hugger]." PX11 (McGovern Dep. II at 375:9–14).

Epidemiologic studies have been well received in mass tort litigation. In the PPA MDL, for example, defense experts attacked an observational study showing an association

[8] Tellingly, 3M has [redacted]. *See, e.g.*, PX45 (3MBH01627569). 3M even offered [redacted]. PX46 (Albrecht_0013733–35).

[9] PX47 (Reed Dep. at 226:12-20); PX11 (McGovern Dep. at 415:8-20); PX48 (Nachtsheim Dep. at 350:4); PX33 (Belani Dep. at 220:22-221:2); PX49 (Albrecht Dep. at 279:16-25).

between a decongestant and hemorrhagic strokes. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1239 (W.D. Wash. 2003). Just like 3M, the defense averred that a single observational study could not show causation and the study was so confounded that it was per se unreliable. *Id.* The Honorable Barbara Rothstein, who now heads the Federal Judicial Center, disagreed and gave a name to this meretricious argument: "Defendants' *ex post facto* dissection of the [study] fails to undermine its reliability." *Id.* at 1240. Almost all studies, she declared, "invariably contain flaws." *Id.*

To be sure, scientists widely recognize that all studies have limitations. Scientists also understand no single study can comprehensively address every potential confounding factor. *See Reference Manual* at 553. Despite their limitations, however, observational studies like McGovern provide valuable information to scientists in estimating risks.[10] For that reason, they are not only the mainstay of epidemiology but the primary form of evidence used to demonstrate causation inside the courtroom. *Id.* at 220; *see also* PX48 (Nachtsheim Dep. at 327:3-328:13) (observational data is "valuable" scientific evidence).

2. The Jeans study does not "confirm" or "prove" that MSSA screening confounded the reduction in DJI reported in the McGovern study.

In light of the Court's *Daubert* ruling and the contradictory testimony of 3M's own epidemiologists, 3M does not seriously attack the McGovern study based on any evidence

[10] 3M's quotation of Dr. Samet's testimony proves the point. Defs.' Mem. at 24 n.9 (using McGovern for a "quantitative estimate" of risk). But like Drs. Jarvis and Stonnington, he also relied on the totality of evidence. *See, e.g.*, PX43 (Samet Dep. at 165:6:9, 167:18–20).

other than the Jeans study.[11] That study, however, does not "confirm" that McGovern was confounded by MSSA screening. Defs.' Mem. at 25–28. Nor was it designed to evaluate the exposure (Bair Hugger) and outcome (DJI) at issue in this litigation. If anything, the study shows that the reduction in DJI reported in McGovern likely arose from replacing Bair Hugger with air-free warming, not the initiation of MSSA screening. *See* PX51 (Borak Dep. II at 34:20-35:4–13) (**admitting that Bair Hugger potentially confounded Jeans**).

The Jeans study took place at Northumbria Health NHS Foundation Trust, which includes three hospitals, one of which is Wansbeck—the hospital in the McGovern study that switched from Bair Hugger to air-free warming. PX52 (Jeans at 1–2). Based on data from all three hospitals, Jeans reported a significant reduction in "PJI," defined as "deep and superficial infection," after the introduction of MSSA screening ($p = 0.03$). *Id.* at 1–3.

Tellingly, the Jeans study did not analyze the effect of Bair Hugger or other warming devices on infection rates. Nowhere in the paper did Dr. Reed or any author comment that changes in MSSA screening was a more likely explanation than Bair Hugger for the infections reported in the McGovern study. Nor did the authors conclude that the positive association between Bair Hugger and DJI was "disproven" or no longer valid. Indeed, Dr.

[11] Dr. Holford testified that there is no evidence to show the change in antithrombotic confounded McGovern, PX50 (Holford Dep. at 293:7–295:13), while the change in antibiotic resulted in reverse confounding. *Id.* at 317:2-323:25. 3M nonetheless continues to insist that McGovern was "likely confounded" by these variables. Defs.' Mem. at 25. Worse, 3M asserts that Holford "concluded that the study data was mistabulated," *id.* at 25 n.10, despite his admission that he had no idea whether the data 3M provided him were the actual data McGovern used, and that the data he used contradicted the published data. *E.g.*, PX50 (Holford Dep. at 128:21-129:6). Any remaining arguments on McGovern were easily addressed in Plaintiffs' *Daubert* briefing. MDL Dkt. 879 at *23–39; Dkts. 779, 802, 975.

Reed relied on McGovern in a study he published just a few months after Jeans, presumably because—as he testified in this MDL—he stands behind the results. *See* PX53 (Reed 2019).

More important, when the McGovern data are removed from the amalgamated data set of Jeans, the significance of the association **disappears** ($p = 0.9$) because the infection rate in each arm of the study is **identical** (1.4%). While this straightforward calculation alone shows that MSSA screening is **not** a confounder, it ultimately corroborates the fact that the significant reduction in DJI reported in McGovern most likely occurred because of the switch from Bair Hugger to air-free warming at Wansbeck, not the initiation of MSSA screening. *See* PX44 (Borak Dep. I at 148:23–25) (testifying that an association is a "start but not a finish" to determining whether a variable is in fact a "confounder"); *see also* PX51 (Borak Dep. II at 35:4–13) (admitting that Bair Hugger "potentially" confounded Jeans).

Setting statistics aside, the Jeans study suffers from additional limitations. The study evaluates whether MSSA screening impacted "PJI" rates based on one time period prior to MSSA screening and another time period after its introduction, but the authors admit that "[p]rior to the introduction of screening there was **no set protocol** for MSSA screening and eradication." PX52 (Jeans at 2). As a result, MSSA screening may still have occurred during the non-screening period and thus "modified the data." PX51 (Borak Dep. II at 57:16). Not to mention the impact of the so-called "Hawthorne Effect" on the data. MDL Dkt. 1024 at *15; *cf.* PX44 (Borak Dep. I at 154:1–10) (Borak had "no idea" if staff knew they were involved in McGovern as data were collected retrospectively, not prospectively).

In addition, "all patients" during the screening period received body wash and nasal spray to use before and after surgery, but the study did not track whether patients used the

products or whether they carried MSSA prior to using the products. PX52 (Jeans at 3–4) (noting as "another limitation"). Nor were patients swabbed prior to surgery to **"confirm eradication on admission**." *Id.* at 2. Without such follow-up data or a complete data set during the pre-screening period,[12] the Jeans study cannot "confirm" that initiation of MSSA screening eradicated MSSA from anyone, much less that it caused the reduction in "PJI." In fact, 23 patients in the screening period still suffered from MSSA infections. *Id.* at 3. That is exactly why the authors admit that MSSA screening "remains a contentious issue" and "improvement in infection rates could have been [due] to **other factors**," such as the removal of Bair Hugger—another reservoir of infection that also causes potentially bacteria-laden particles to travel to the sterile field—from operating rooms. *Id.* at 3–4; *see also* PX51 (Borak Dep. II at 35:4-13) (admitting Bair Hugger may have confounded Jeans).

What's more, the Jeans study is an **observational study**. PX52 (Jeans at 4) ("A key limitation of our study was that the groups were not randomized."). In stark contrast to its initial *Daubert* motion, where 3M attacked McGovern because it was observational rather randomized, 3M now paradoxically asserts that the observational Jeans study **"confirms"**

[12] Two facts show that the Jeans study underreported infection data during the pre-screening period. First, the study period started on January 1, 2007, more than a year before "full-time surveillance" began on July 1, 2008. PX47 (Reed Dep. at 46:11–20). Second, the number of operations in the four-year post-screening period is three times the size of the three-year pre-screening period. *See* PX52 (Jeans at 3, Table 3). Thus, while the authors used the "complete data **available**," they did not review the total number of surgeries and infections that actually occurred during the pre-screening period. *See* PX51 (Borak Dep. II at 43:5). This is yet another reason that the Jeans study does not confirm that MSSA screening confounded McGovern. PX47 (Reed Dep. at 64:2–7) (it would be "very unreliable" to use data collected before July 1, 2008); PX50 (Holford Dep. at 247:4–13) (complete DJI data was not available until July 1, 2008, if not as late as January 1, 2009).

and **"proves"** that MSSA screening caused the drop in DJI and confounded McGovern. *Compare* Defs.' Mem. at 25–26 *with* MDL Dkt. 750 at *17 (McGovern "was an observational study, meaning that it was not blinded and controlled like a clinical study"). This claim is disingenuous at best and deceptive at worst. Either way, it should be rejected.

3M's argument also belies epidemiology. Both Plaintiffs and 3M's experts have stated that observational studies cannot "prove" causation; by definition, they show only an association. *See Reference Manual* at 552, 598 ("An association is not equivalent to causation . . . Epidemiology cannot prove causation; rather causation is a judgment for epidemiologists and authors."); *see also* PX50 (Holford Dep. at 375:12–17) (testifying that "deciding whether associations are causal typically is not a matter of statistics alone, but also rests on scientific judgment"). Indeed, as 3M once recognized but now ignores, "to prove cause in a scientific sense would require a massive controlled, blinded study." MDL Dkt. 750 at *19 n.4. Because Jeans cannot "prove" the McGovern study was confounded by MSSA screening, **as 3M's own epidemiologist admits**, this new study can only suggest (at best) a "potential impact," as the same sources cited by 3M explain.[13] DX2 (2018 ICM at 112) (stating Jeans revealed only "potential impacts"); PX51 (Borak Dep. II at 13:2–25) (conceding Jeans study "does not prove causation" because "it's an observational study").

Finally, even if the Jeans study could confirm that MSSA screening reduces "PJI" notwithstanding its methodological limitations, reconsideration of general causation is still

[13] Similarly, McGovern never "expressly noted" that protocol changes confounded the study. Defs.' Mem. at 25. Like Jeans, the authors simply stated the data were "observational and **may be** confounded by other infection control measures." PX25 (McGovern at 1543).

unwarranted for at least four reasons. *First*, the study investigated "PJI," which the authors defined as both "**deep and superficial infection**." PX52 (Jeans at 3) (emphasis added). The McGovern study, however, involved only the former. PX25 (McGovern at 1537); PX50 (Holford Dep. at 96:17–20). Because the etiology distinctly differs between these infections, 3M's epidemiologist admitted at his deposition that Jeans cannot "confirm" anything about the reduction in deep joint infection rates reported in McGovern. PX51 (Borak Dep. II at 36:10-14); PX1 (Jarvis Rpt. at 6-7, 15-17); PX50 (Holford Dep. at 305:3-306:10) (admitting the two types of infections are "not the same thing"); PX44 (Borak Dep. I at 201:17-202:4) (stating it would be improper to conflate different types of infection).[14]

Second, the Jeans study reported a significant reduction in "PJI" rates in hip cases, but no such effect in knee cases. PX52 (Jeans at 3). In fact, MSSA screening resulted in **"no change in overall infection rates [or] MSSA infection rates"** in knee cases. *Id.* at 4. Thus, assuming for the sake of argument that the Jeans study could "confirm" that MSSA screening confounded McGovern, it would only affect hip arthroplasties. PX1 (Jarvis Rpt. at 8) ("One cannot generalize from one surgical procedure (i.e., cardiac or general surgery) to another (orthopedic or specifically to total knee arthroplasty or total hip arthroplasty procedures)."); PX51 (Borak Dep. II at 38:3–6) (Jeans did not find DJI reduction in knees).

Third, still assuming that MSSA screening confounded the reduction in DJI reported in McGovern, that effect cannot account for the entire reduction. *See* PX2 (Samet Rpt. at

[14] To the extent Jeans used "multivariate analysis," unlike McGovern, 3M never mentions that the statistical calculation improperly lumped together "deep and superficial infection." PX52 (Jeans at 3). 3M also omits that the multivariate analysis did not find MSSA screening to be a "significant predictor" of "overall infection." *Id.*; Defs.' Mem. at 26 n.11.

12) ("For the sole explanation to lie with confounding, there would need to be sufficient positive confounding . . . to explain [the magnitude of the association] fully."). McGovern reported an "elevated infection odds ratio of 3.8,"[15] PX25 (McGovern at 1537), while the **odds ratio in Jeans is only 1.37**—less than half the effect from using air-free warming instead of Bair Hugger. Stated differently, the risk of using Bair Hugger remains above 2.0 even if the reduction in "PJI" reported in the Jeans study is presumed to be due entirely to the initiation of MSSA screening rather than "other factors" such as air-free warming.[16] *See* PX52 (Jeans at 4). The Bair Hugger, after all, does not discriminate between the bugs it blows. *See id.* at 3 (noting higher rate of non-MSSA infection **after** MSSA screening).

An odds ratio greater than 2.0 proves causation by itself. On cross-examination, Plaintiffs' counsel asked Dr. Holford whether he agreed with the following statement: "If the incidence of disease in an exposed group is more than twice the incidence in the unexposed group [odds ratio > 2.0], the probability that exposure to the agent caused [the same disease] in a similarly situated individual is also greater than 50%." PX50 (Holford Dep. at 225:19–226:1). He agreed—and for good reason. *Id.* Numerous courts, including this one, have stated that an odds ratio of "**2.0 or greater provides reliable evidence of *specific* causation**." *In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1078 (D. Minn.

[15] The odds ratio is likely much larger than 3.8 because, as Dr. Holford conceded, switching antibiotics during the study period reduced DJI for patients who used Bair Hugger while it increased DJI for patients who used air-free warming. PX50 (Holford Dep. at 317:2–6).

[16] The same result obtains when controlling for MSSA infections in McGovern. Removing the 11 MSSA infections reported in Table III reduces the total number of infections in the Bair Hugger period from 32 to 21, resulting in a 2.49 odds ratio. PX25 (McGovern at 1542).

2008) (citing *Reference Manual* at 384); *Manko v. United States*, 636 F. Supp. 1419, 1434 (W.D. Mo. 1986) ("A relative risk greater than '2' means that the disease more likely than not was caused by the event."), *aff'd*, 830 F.2d 831 (8th Cir. 1987); *Liable v. Sec'y of Health & Human Servs.*, 2000 WL 1517672, at *15 (Fed. Cl. Sept. 7, 2000) (collecting appellate cases). 3M's own expert testimony therefore **proves as a matter of law** that Bair Hugger causes DJI even assuming that MSSA screening somehow confounded McGovern.

Fourth, following publication of Jeans in July 2018, co-author Dr. Reed published another study in January 2019, which found that "[l]aminar airflow alone does not guarantee ultraclean air because it is critically dependent on environmental factors" such as "patient warming devices." PX53 (Reed 2019 at 5). Citing McGovern, Dr. Reed further stated that forced-air warming devices were "associated with substantially higher numbers of simulated particles over the operative field and **substantially higher rates of post-operative [infection]**." *Id.* at 6. (emphasis added). Dr. Reed thus recommended using a "resistive heating mattress or blanket over a forced-air warming device," without even citing Jeans. *Id.* Contrary to 3M's argument, Jeans does not "confirm" McGovern was confounded by MSSA screening when the most recent literature says the opposite. PX54 (Jarvis *Trombley* Rpt. at 16) (discussing Reed 2019); *cf.* PX51 (Borak Dep. II at 72:15-25).

In sum, 3M's motion is a repeat of its initial *Daubert* motion: 3M yet again fails to cite even **one epidemiologic study** "proving" Bair Hugger does not increase DJI; nor has the scientific community called for the retraction of McGovern.[17] PX51 (Borak Dep. II at

[17] 3M's reliance on *Viagra*, *PPA*, and *Mirena*, is misplaced. *In re Viagra*, 658 F. Supp. 2d 936, 944 (D. Minn. 2009) ("Plaintiffs concede there are acknowledged inaccuracies in the

53:7–10). Instead, 3M requests reconsideration of general causation based on Jeans—**a sole study that does not address the relevant exposure (Bair Hugger) or outcome (DJI) at issue in this litigation**. And even if 3M could cite an epidemiologic study finding that Bair Hugger does not cause DJI, that would still not be enough to reverse general causation given the company's dispositive admission that [redacted] PX55 (3MBH00001336), and this Court's correct ruling that Plaintiffs' medical experts "need not rule out every alternative explanation for [McGovern's] drop-off in infections." MDL Dkt. 1024 at *9. Competing studies are fertile ground for cross-examination, as the *Gareis* trial proved and future cases will too. PX18 (TT at 779:2-782:7) (examining Dr. Jarvis on potential confounding factors); *see also Johnson*, 754 F.3d at 564 (concluding that failure to consider confounders did not undermine reliability of expert testimony); *Hose*, 70 F.3d at 976 (because "experts often disagree on diagnosis and causation, questions of conflicting evidence must be left for the jury's determination").[18]

published study that need to be corrected."); *In re PPA*, 289 F. Supp. 2d at 1239 (rejecting "*ex post facto* dissection" of study for reasons noted *supra*); *In re Mirena*, 341 F. Supp. 3d 213, 252–53 (S.D.N.Y. 2018) (excluding expert who did not consider contrary studies). So too is 3M's reliance on the *Reference Manual*, which it cites for the phony proposition that epidemiologic studies are only "good evidence" of causation under two conditions, Defs.' Mem. at 27–28, blithely disregarding the **third condition** of biological plausibility, which is met here given the mountain of mechanistic evidence. *Reference Manual* at 221; *see* PX2 (Samet Rpt. at 16) ("There is a coherent body of evidence supporting both pathways.").

[18] Because the McGovern study remains a valid epidemiologic study notwithstanding the Jeans study, Plaintiffs need not focus on the second premise of 3M's argument, which is equally flawed. *See, e.g.*, *Bonner*, 259 F.3d at 929 ("there is no requirement that published epidemiologic studies supporting an expert's opinion exist in order for the opinion to be admissible"); *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 728 n.6 (N.D. Ohio 2011) (circuit survey). To the extent some cases hold otherwise, they do so where an expert fails to use epidemiologic evidence to rebut contrary epidemiologic evidence. Defs.' Mem.

IV. THE 2018 ICM IS ONLY ONE PIECE OF THE TOTALITY OF EVIDENCE AND DOES NOT PRECLUDE EXPERT OPINIONS ON CAUSATION

3M further argues that the 2018 ICM—a delegation funded by 3M, chaired by 3M's consultant Dr. Parvizi, authored by 3M's proponent Dr. Karam, and edited by 3M's orthopedic expert Dr. Mont—presents "compelling circumstances" to reconsider general causation.[19] Defs.' Mem. at 3–4. It does not. For starters, 3M's reliance on the 2018 ICM is **procedurally improper**. 3M's request for leave to move for reconsideration identified "three" pieces of evidence: Dr. Elghobashi's trial testimony; the case-specific evidentiary ruling in *Gareis*; and the Jeans study. MDL Dkt. 1428 at *1–2. Because 3M never mentioned the 2018 ICM, it cannot bootstrap this hearsay evidence into its motion for reconsideration. MDL Dkt. 1608 at *1 (granting leave based on "Elghobashi's trial testimony [and] a study published in 2018"); *see Olson v. Kambiri*, 2014 WL 5437062, at *10 (D. Minn. Oct. 24, 2014) (denying procedurally improper motion for reconsideration).

Motions for reconsideration also "cannot be used to relitigate old issues." *Dale v. U.S. Dep't of Agric.*, 838 F. Supp. 1346, 1348 (D. Minn. 1993). Yet 3M already argued in its first *Daubert* motion that the 2013 ICM found that "no studies have shown an increase

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at 24 (citing *In re Zoloft Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 493–99 (E.D. Pa. 2016) (same)). Here, however, 3M has repeatedly refused to conduct an epidemiologic study to rebut McGovern, despite [redacted] PX56 (3MBH01330587) [redacted]; PX57 (3MBH01944765) (Van Duren refusing to conduct study of Bair Hugger's impact on DJI because it would be a bad "career move").

[19] *See* PX58 (3M is a "platinum sponsor" of the 2018 ICM); PX59 (3MBH01623551) ([redacted] PX60 (3MBH02329969) ([redacted]).

in [infection] related to the use of these devices." MDL Dkt. 750 at *30 (citing 2013 ICM). The 2018 ICM is much weaker for 3M. Instead of finding that **no** studies have shown an increased risk of DJI, the 2018 ICM found "no evidence to **definitively** link FAW to increased risk of [DJI]."[20] DX2 at 112 (emphasis added). 3M's reliance on the 2018 ICM is thus improper. *Dalton v. Hawkins*, 2013 WL 2250989, at *1 (D. Minn. May 22, 2013).

Regardless, the fact that the 2018 ICM found no evidence "definitively" linking forced-air warming to infection is unremarkable. No evidence can provide such a link other than high-level evidence such as a "randomized prospective trial," as the 2018 ICM made clear in recognizing the "theoretical risk posed by FAW." DX2 at 114; MDL Dkt. 750 at *19 n.4. That is precisely why epidemiology allows Plaintiffs' medical experts to make causal inferences by applying the totality of evidence to landmark guidelines such as the Bradford Hill criteria. *See Reference Manual* at 551–53 (stating that epidemiologic studies rather than randomized controlled trials are the primary form of scientific evidence used to demonstrate causation in the courtroom); *see also* PX50 (Holford Dep. at 375:12–17) (conceding that causal determinations depend on expert "judgment," not absolute proofs).

[20] Like the 2013 ICM, the 2018 ICM addressed whether the change in antithrombotic confounded the McGovern study. And like the 2013 ICM, the 2018 ICM did not "confirm" the Jensen study caused the drop in DJI rates reported in McGovern. *See* DX2 at 112 ("potential impact"); *see also* PX50 (Holford Dep. at 293:7-295:13) (admitting that the scientific literature does not suggest an *a priori* relationship between antithrombotic and DJI); PX47 (Reed Dep. 215:7–18) (testifying that Jensen does not show McGovern was confounded by changing the antithrombotic); PX48 (Nachtsheim Dep. at 347:7-348:1).

Thus, the 2018 ICM's failure to find "definitive" evidence of causation does not doom the opinions of Plaintiffs' medical experts.[21] *See Daubert*, 509 U.S. at 590; *cf.* Defs.' Mem. at 3, 29. Nor does it mean those opinions are not "generally accepted." *Cf. id.* at 31. It does highlight, however, [redacted]. *See, e.g.*, PX56 (3MBH01330587). And it also highlights 3M's *tu quoque* at every step of this litigation, as the company continues to brazenly tout the 2018 ICM and other "scientific" evidence that it manufactured while simultaneously criticizing evidence allegedly "sponsored or orchestrated by [its] competitor." MDL Dkt. 750 at *4.

The 2018 ICM does not preclude Plaintiffs' experts from inferring general causation and in fact furthers that inference by recognizing the "theoretical risk posed by FAW." DX2 at 114. 3M attempts to dodge this issue, arguing that the delegation relied on "the same scientific studies" as Plaintiffs' experts. Defs.' Mem. at 29–30. Not so. The 2018 ICM cites **some but not all** of the same studies and excludes, by way of example, the relevance of heater-cooler studies and the CDC's remarks on the same. *E.g.*, PX61 (CDC 2015 Proceedings at 27) (recommending that **"nothing that blows air should be in the operating room"**). *Compare* DX2 (25 studies) *with* PX2 (Samet Rpt. Ex. C) (96 studies); PX1 (Jarvis Rpt. at 26–31) (68 studies); PX3 (Stonnington Rpt. at 9–11) (46 studies). Nor does the ICM cite any of the damning documents 3M produced in this case, including the company's [redacted], PX62

[21] 3M's obfuscation of the 2018 ICM is not limited to that finding. 3M also says the ICM found that "normothermia has been shown to reduce perioperative complications including SSI," even though the ICM stated that "further research is needed to establish correlation between patient's temperature and SSIs in the field of orthopedic[s]." DX2 at 115–16.

(3MBH00297660), and that the company has known since at least 1994 that [redacted] *E.g.*, PX63 (3M00554405).

Dr. Samet, however, considered **196 independent sources of evidence**—ranging from scientific literature, to internal documents, to the depositions of party and non-party witnesses—in determining that Bair Hugger can cause infection. PX2 (Samet Rpt. Ex. C).

Additionally, the ICM delegates may be well-qualified orthopedists in their own right, but that does not transform them into world-renowned experts trained in causal inference, unlike Plaintiffs' medical experts; nor did they apply the Bradford Hill criteria or any other well-accepted methodology for analyzing whether Bair Hugger in fact causes infection. In the final analysis, the 2018 ICM is merely **one piece of limited evidence** that 3M attempts to balkanize from the **totality of evidence**. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 2017 WL 1833173, at *13 (N.D. Ill. May 8, 2017) ("[A]lthough [some regulatory bodies] may have a different interpretation of the studies relied upon by plaintiffs' experts, it is left to the trier of fact, not the reviewing court, to decide how to weigh the competing expert testimony."); *In re Celexa & Lexapro Prods. Liab. Litig.*, 927 F. Supp. 2d at 765 (refusing to exclude expert testimony on same grounds).

Finally, 3M conflates *Daubert* with *Frye-Mack* in asserting that the ICM proves the *opinions* of Plaintiffs' experts are inadmissible because they are not generally accepted.[22] Defs.' Mem. at 31. Before *Daubert*, scientific evidence was admissible only if the methods underlying it were "sufficiently established to have gained general acceptance in the

[22] In any event, *Frye-Mack* only requires "general acceptance" of *methods*, not *opinions*.

particular field in which [they] belong." *Gier v. Educ. Serv. Unit 16*, 66 F.3d 940, 943 (8th Cir. 1995) (quoting *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). *Daubert*, however, eliminated general acceptance as an "absolute prerequisite." *Jaurequi v. Carter*, 173 F.3d 1076, 1081 (8th Cir. 1999). Any "rigid general acceptance requirement," as raised by 3M, is "at odds with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to opinion testimony." *E.g.*, *Lauzon*, 270 F.3d at 691.

Moreover, the lack of evidence "definitively" linking forced-air warming devices to infection does not mean that the opinions of Plaintiffs' medical experts are novel, particularly because the 2018 ICM noted that the "literature is conflicting." DX2 at 114. As Dr. Holford explained on behalf of 3M, causal determinations depend on the judgment of properly trained scientists, not absolute proofs. PX50 (Holford Dep. at 375:12–17). Even without "definitive" evidence that Bair Hugger causes infection, other scientific groups, including a minority of the 2018 ICM, have concluded that Bair Hugger causes infection.

The French Society of Microbiologists, for example, prohibits surgeons from using Bair Hugger precisely **"because of its high risk for patients to develop a surgical site infection."** PX64 (3MBH00799540); *accord* PX65 (3MBH01975265) [redacted]. The Bone and Joint Center has also unequivocally announced [redacted] PX66 (3MBH01332558). Even 3M's Director of Clinical Research opined [redacted] PX2 (Samet Rpt. Ex. C at 11) (citing 3MBH00001336); *see also 3M Innovative*

Prop. Co. v. GDC, Inc., 2016 WL 3976589, at *10 (D. Minn. July 22, 2016) (admitting expert testimony as challenge to general acceptance involved "conflicting evidence").[23]

While additional examples abound,[24] the fact remains that the opinions of Plaintiffs' experts are not novel, and even if they were, that is not enough to exclude them. *Bonner*, 259 F.3d at 929 ("The district court could not exclude [expert] testimony simply because the conclusion was novel."); *Lauzon*, 270 F.3d at 691 (rejecting such a rigid requirement).

V. THE COURT SHOULD DECLINE TO CERTIFY ITS ORDER FOR APPEAL BECAUSE NONE OF THE § 1292(b) FACTORS ARE SATISFIED

If the Court denies the motion, which it should for any one of the reasons discussed above, 3M requests certification of the order under 28 U.S.C. § 1292(b). None of the criteria for certifying an appeal, however, are "readily satisfied" here. Defs.' Mem. at 32.

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[23] 3M's cursory citation to the "prior conclusions of AORN, ECRI, the Duke Infection Control Outreach Network, [and] the FDA," only highlights the need for a jury to weigh the evidence. MDL Dkt. 879 at *55–61 (distinguishing articles); *cf., e.g.*, PX67 (2017 FDA Safety Alert at 4) (instructing doctors to direct "exhaust away from the surgical field to mitigate the risk of aerosolizing [bacteria] into the sterile field and exposing the patient").

[24] *See, e.g.*, PX68 (Avidan 1997) ("We conclude that these warming devices are a potential **source of nosocomial infection**."); PX5 (Baker 2002) ("[T]here seems insufficient evidence to justify the routine use of forced air warming units as an intraoperative measure during ultraclean orthopaedic surgery."); PX69 (Moretti 2009) (studies have found "a higher incidence of nosocomial infections in patients kept warm using Bair Hugger"); PX70 (National Institute for Health and Care Excellence recommending air-free warming instead of forced-air warming); PX71 (3MBH00024733) ([redacted]); PX12 (3MBH01260231) ([redacted]); PX72 (3MBH00932516) ([redacted]); PX11 (McGovern Dep. II at 375:9–14) (peer-reviewer stating that the McGovern study "support[s] the contention that there is a serious issue to be addressed with forced-air warming devices"); PX62 (3MBH00297650) ([redacted]); PX73 (3MBH00500237) ([redacted]).

First, the admissibility of Plaintiffs' medical experts does not turn on a "controlling question of law." 28 U.S.C. § 1292(b). 3M argues that *Glastetter* created a stricter standard for admitting expert evidence compared to the "more permissive 'fundamentally unsupported' standard cited in the Court's Order," but it misreads that *per curiam* opinion. Defs.' Mem. at 32 (citing *Children's Broad. Corp.*, 357 F.3d at 864; *Hose*, 70 F.3d at 974).

In *Glastetter*, the plaintiff's expert opined that a drug could cause strokes because it caused vasoconstriction. But not a **shred** of reliable scientific evidence supported the expert's unusual premise. *Glastetter*, 252 F.3d at 990. The Eighth Circuit thus affirmed the exclusion of the expert's differential diagnosis as it was "scientifically invalid." *Id.* at 989.

Since *Glastetter*, neither the Eighth Circuit nor any other court has interpreted that decision as imposing a heightened standard for an obvious reason: "scientifically invalid" opinions are necessarily also "fundamentally unsupported" opinions. For that reason, the Eighth Circuit has repeatedly cited *Glastetter* in evaluating whether expert testimony is "fundamentally unsupported." *Bonner*, 259 F.3d at 929–30 (citing *Glastetter* and *Hose* in evaluating whether expert testimony was sufficiently "reliable" under *Daubert*); *Johnson*, 754 F.3d at 562–63 (similar). So too have courts in this District. *In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d at 1078 (citing *Glastetter* and *Bonner*); *In re Baycol Prods. Litig.*, 2009 WL 8154265, at *4–5 (D. Minn. Apr. 8, 2009) (same). Therefore, because *Glastetter* did not create a stricter standard than the so-called "fundamentally unsupported standard" this Court correctly cited in its *Daubert* order, there is not a "controlling legal question."

Second, assuming *Glastetter* created a heighted standard, there is not "substantial ground for difference of opinion." According to 3M, *Glastetter* contradicts earlier cases

establishing the "fundamentally unsupported standard." Defs.' Mem. at 32–33. And therein lies the rub. The "cardinal rule" in this Circuit is that "one panel is bound by the decision of a prior panel." *Weed v. Jenkins*, 873 F.3d 1023, 1029 (8th Cir. 2017). Thus, "when faced with conflicting panel opinions, **the earliest opinion must be followed** as it should have controlled the subsequent panels that created the conflict." *Mader v. United States*, 654 F.3d 794, 800 (8th Cir. 2011) (en banc). So even if *Glastetter* created a "conflicting" standard, the earlier line of cases establishing the "fundamentally unsupported standard" controls here.[25] *See Graham v. Barnette*, 2018 WL 6592666, at *7 n.6 (D. Minn. Dec. 14, 2018) (Ericksen, J.); *cf. United States v. Huston*, 744 F.3d 589, 592 (8th Cir. 2014) (affirming this Court's order because "[a]fter *Mader*, we must follow *Brooks*, the earlier opinion"). The sole case that 3M cites proves as much. *See In re Blue Cross Blue Shield Antitrust Litig., MDL 2406*, 2017 WL 588445, at *3–4 (N.D. Ala. Feb. 14, 2017) (denying certification because prior panel rule defeated argument regarding conflicting authority).

Third, certification would not materially advance the termination of this litigation because *Glastetter* does not control, much less change the standard this Court used in denying 3M's *Daubert* motion. Even if it did, the opinions of Plaintiffs' medical experts rest on "scientifically valid" methodologies. In contrast to *Glastetter*, where the expert failed to cite **one** epidemiologic or experimental study reinforcing the sole premise of his opinion, numerous peer-reviewed studies support the opinions of Drs. Samet, Jarvis, and

[25] *Hose* came after *Daubert*, so the only exception to the prior panel rule does not apply. *U.S. v. Taylor*, 803 F.3d 931, 933 (8th Cir. 2015) ("prior panel ruling does not control when the earlier panel decision is cast into doubt by an intervening Supreme Court decision").

Stonnington. Not to mention that 3M's own documents admit Bair Hugger "increases the risk" of DJI, unlike in *Glastetter*, 252 F.3d at 990–91. PX2 (Samet Rpt. Ex. C at 11) (citing 3MBH00001336). Properly understood, application of *Glastetter* would not therefore end this litigation. *Johnson*, 754 F.3d at 563 (reversing this Court's strict reading of *Glastetter*).

Finally, this is not the "perfect" time to certify the issue of general causation. Defs.' Mem. at 33. 3M recognizes, as it must, that it has **already cross-appealed** this Court's *Daubert* order. *Id.* Presumably, 3M will incorrectly argue in that appeal just as it does here that this Court erred in applying the admissibility standard of *Children's Broad.* instead of *Glastetter*. Thus, 3M's request to certify the issue is not only pointless, it does not involve a controlling legal question or present substantial ground for difference of opinion. Nor would certifying the Court's ruling allow the *Gareis* panel to consider any additional evidence at this late stage of the appeal. The Court should therefore deny 3M's request for certification. *See, e.g.*, *Blue Cross Blue Shield Antitrust Litig.*, 2017 WL 588445, at *3–4.

CONCLUSION

Plaintiffs respectfully ask the Court to deny 3M's motion for reconsideration of general causation and its alternative request for certification under 28 U.S.C. § 1292(b).

Respectfully submitted,

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